



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/596,784	06/19/2000	Adam J. Bogdanove	19603/3296 (CRF D-2098B)	3745
7590	03/22/2002			
Michael L Goldman Nixon Peabody LLP Clinton Square P O Box 31051 Rochester, NY 14603			EXAMINER	
			BUGAISKY, GABRIELE E	
			ART UNIT	PAPER NUMBER
			1653	
DATE MAILED: 03/22/2002				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/596,784	BOGDANOVA ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Gabriele E. BUGAISKY	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_.  
 2a) This action is **FINAL**.                  2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 17-28,38 and 39 is/are pending in the application.  
 4a) Of the above claim(s) 20-28 is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_ is/are allowed.  
 6) Claim(s) 17,19,38 and 39 is/are rejected.  
 7) Claim(s) 18 is/are objected to.  
 8) Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 11) The proposed drawing correction filed on \_\_\_\_ is: a) approved b) disapproved by the Examiner.  
 If approved, corrected drawings are required in reply to this Office action.  
 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
 \* See the attached detailed Office action for a list of the certified copies not received.  
 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
 a) The translation of the foreign language provisional application has been received.  
 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>3</u> . | 6) <input type="checkbox"/> Other:  |

### **DETAILED ACTION**

The amendment of 12/19/01 is acknowledged. Claims 40-43 have been cancelled.

Claims currently pending are 17-28 and 38-39; claims 20-28 remain withdrawn from consideration.

The amendment filed 12/19/01 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: a hybridization medium which includes about 1M NaCl. It was stated in the response that support for the amendment could be found at page 18, lines 3-6. The Examiner has reviewed that section of the specification; the hybridization conditions are not “about 1M NaCl”, The stated conditions include 1M NaCl, not ‘about 1M NaCl.’ Applicant is required to cancel the new matter in the reply to this Office Action.

### ***Information Disclosure Statement***

The Examiner thanks Applicants for providing new copies of the reference cited in paper #3. He *et al.* (120) has been crossed out as it is already of record. The citation to references 14, 64, 68, is not complete. Applicants are requested to furnish a complete citation for those references.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 17, 19 and 38-39 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated HR eliciting protein comprising SEQ ID NO:2 or 4, or encoded by a nucleic acid whose full complement hybridizes at 65° C in a medium which includes 1M NaCl to a DNA molecule comprising a nucleotide sequence of SEQ ID NO: 1 or 3 and compositions containing the protein, does not reasonably provide enablement for any isolated HR eliciting protein, wherein the complement of a nucleic acid encoding that protein hybridizes at 65° C in a medium which includes 1M NaCl to a DNA molecule comprising a nucleotide sequence of SEQ ID NO: 1 or 3. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. The Examiner has carefully considered Applicants arguments and finds them convincing to the extent that the specification is enabling, provided that the full complement of the encoding nucleic acid hybridizes under stringent conditions. It is deemed that undue experimentation would be involved in obtaining proteins encoded by nucleic acids of which only a small portion (e.g., 15 contiguous nucleic acids) of the complement hybridizes under stringent conditions.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 17, 19 and 38-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "about" is relative, and without a definition in the specification, it must be interpreted as indefinite. The metes and bounds of the claimed invention are not clear because one does not know if, e.g., 0.8M NaCl is considered about 1.0M NaCl.

Claims 19, 38 and 39 are included in this rejection, as they depend from claim 17 and do not clarify the ambiguity. It also is not clear whether claim 19 attempts to broaden claim 17. It is suggested the claim be amended to reflect the limitations recited in the independent claim.

***Claim Rejections - 35 USC § 102***

The rejection of claims 17, 19 and 38 under 35 U.S.C. 102(b) as being anticipated by He *et al* is withdrawn, based upon the amendment.

***Claim Rejections - 35 USC § 103***

The rejection of claim 39 under 35 U.S.C. 103(a) as being unpatentable over He *et al.* is withdrawn, based upon the amendment.

***Conclusion***

No claims are allowed.

Claim 18 remains objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 1653

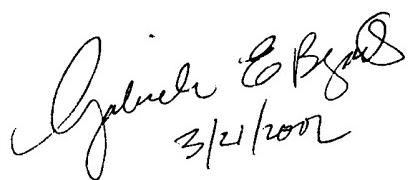
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Gabriele E. Bugaisky, Ph.D. whose telephone number is (703) 308-4201. The Examiner can normally be reached from 8:15 AM to 12:15 AM on Mondays and from 8:15 AM to 1:15 PM on other weekdays.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Christopher S. F. Low, can be reached at (703) 308-2923.

Papers related to this application may be submitted by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center number is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center receptionist whose telephone number is (703) 308-0196.



3/21/2001

GABRIELE E. BUGAISKY  
PATENT EXAMINER